 K012759

Premarket Notification [510(K)] Summary

Submitter:

JAN 17 2002

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Contact:

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Date Prepared:

January 14, 2002

Proprietary Name:

InSpectra™ Tissue Spectrometer System, Model 325

Common Name:

Tissue Spectrometer

CFR Reference:

21CFR§870.2700

Class:

II

Product Code:

74 MUD

Predicate Device:

Biospectrometer - NB Oximeter, Model 1111 by Hutchinson Technology, Inc. (K963903)

Description:

This premarket notification (510(K) Notification) is submitted to obtain marketing clearance for the Hutchinson Technology, Inc. BioMeasurement Division "InSpectra™ Tissue Spectrometer System, Model 325" (hereinafter referred to as **InSpectra™**).

The **InSpectra™** is designed to estimate the percent oxygen saturation of hemoglobin in a volume of tissue (StO_2). This value is a reflection of localized perfusion of that tissue. The **InSpectra™** is a modified version of the previously cleared Hutchinson Technology;

Inc. (HTI) Biospectrometer NB Oximeter, Model 1111, and represents upgrades in hardware and software, while relying on the same principles of operation.

The **InSpectra™** is composed of the following components.

- Monitor: The "**InSpectra Tissue Spectrometer**" houses the user interface, and associated electronics. It serves as the analytical and display instrument.
- Patient Cable: The "**Optical Integrator**" transmits light to and from the Tissue Spectrometer and the patient;
- Patient Interface: The "**OptoShield™**" interface is a disposable pad that mechanically attaches to the distal end of the Optical Integrator. Its bottom has an adhesive backing for attachment to the patients skin for continuous monitoring. Until ready for use, the adhesive is covered with a liner to allow intermittent measurements.
- Printer: A "**Thermal Printer**" may be used to print out the StO_2 results for time trending and recording purposes.
- Optical Converter: An "**Optolink™**" RS232 Optical Converter - Model 300 is a device that converts the optical output of the Spectrometer to an electrical signal.
- Set-up Accessories: An "**OptoCheck™**" module as well as both "High" and "Low" "**Single Point References**" are provided to verify proper system operation.

Intended Use:

Hutchinson Technology Incorporated's InSpectra™ Tissue Spectrometer System, Model 325, is a non-invasive monitoring system that measures an approximated value of percent hemoglobin oxygen saturation in tissue (StO_2).

The InSpectra™ Tissue Spectrometer with 12 to 25 mm probes is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

The InSpectra™ Tissue Spectrometer System is intended to noninvasively and continuously measure hemoglobin oxygen saturation: in the upper extremity, shoulder, or lower extremity with 12 mm to 25 mm probes.

The value of these measurements in disease states has not been demonstrated.

Technological Characteristics:

The fundamental changes from the predicate device include:

- New hardware and software platforms for the Tissue Spectrometer (i.e., monitor)
- Revised patient cables
- Increased measurement range for the patient cables (i.e., depths of measurement)
- Modified calibration modules
- Inclusion of a printer to provide results in a hardcopy format
- A reworded indication-for-use statement (note: the fundamental intended use is retained)

Substantial Equivalence Rationale:

The HTI Biospectrometer NB Oximeter Model 1111 serves as the predicate device for purposes of this submission. The **InSpectra™** and the Biospectrometer NB Oximeter share the intended use of measuring an approximated value of percent oxygen saturation of hemoglobin in a volume of tissue. In addition, they share the same design principles that incorporate a light source, fiber optic cables (which direct the light to and from the target tissue), optical detectors, analysis of specific wavelengths, and a software algorithm that provides the estimate of hemoglobin oxygen saturation.

Changes to the device necessitating this submission include component upgrades, a revised electronics layout, an integrated microprocessor, and revised software required by the changes in components and microprocessor. The basic operating principles and measurement algorithm remain the same. There have also been improvements to the patient cable and interface, making them easier to manufacture and improving their performance.

Test Reports:

Hutchinson Technology, Inc. has conducted extensive testing of the new electronic components to verify adherence to requirements. The devices that comprise the system have been tested individually to verify operation per design intent. Software has been evaluated at the unit, integration, and system-level to document proper performance. The **InSpectra™** has been subjected to both in vitro as well as in vivo testing to validate satisfaction of functional specifications.

A human study comparing device performance between the **InSpectra™** and the predicate system demonstrated equivalent clinical performance.

Conclusion:

Hutchinson Technology, Inc. concludes that the **InSpectra™** is substantially equivalent to the Biospectrometer - NB Model 1111.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Mr. Joseph Ortner
Hutchinson Technology Incorporated
40 West Highland Park Drive NE
Hutchinson, MN 55350-9784

Re: K012759
InSprectra™ Tissue Spectrometer System, Model 325
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: 74 MUD
Dated: December 7, 2001
Received: December 10, 2001

Dear Mr. Ortner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name: K012759

InSprectra™ Tissue Spectrometer System, Model 325

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012759

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)